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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,227	08/31/2000	Juergen Hilman	PLOVIN-1-A	5622

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/654,227

Applicant(s)

HEIL ET AL.

Examiner

Mojdeh Bahar

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003 and 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935.C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-7, 9-14, 16-19, 21-22, 36-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 3-7, 9-14, 16-19, 21, 22 and 36-56 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on January 21, 2003 and March 19, 2003 have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 recites the limitation "composition". There is insufficient antecedent basis for this limitation in the claim in so far as it depends from claims 47 or 49.

Claims 7, 9, 45, 47-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite a particular method, "USP Paddle method" as well as "USP XXIII Paddle method". It is not clear what these methods designate. What are the method steps involved? How do the two methods differ from one another?

Objections

The attempt to incorporate subject matter into this application by reference to "USP Paddle method" as well as "USP XXIII Paddle method" is improper because the applicant seems to be incorporating this "method" which is considered essential material herein by reference to a

source other than a US patent or patent application. Note that this is an improper incorporation by reference of "essential material".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-7, 9-14, 16-17, 36-41, 43-47 and 50-56 rejected under 35 U.S.C. 103(a) as being unpatentable over Gast (WO 98/04269) and Elliesen et al. (USPN 5,922,349).

Gast (WO 98/04269) teaches a combination composition comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estradiol^a, and pharmaceutically acceptable carriers and excipients, see page 9, lines 19-33 and claims 1, 18-22. Gast (WO 98/04269) also teaches a contraceptive kit adapted for daily oral administration which comprises 28 separate dosage units each containing drospirenone and ethinyl estradiol with 3-5 dosage units being a non-contraceptive placebo, see page 10, lines 15-24 and claims 25-28 in particular.

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Elliesen et al. (USPN 5,922,349) teaches an orally administerable pharmaceutical composition comprising ethinyl estradiol (5-15 microgram) as the estrogen and drospirenone (1-3 mg) as the progestogen. Elliesen further teaches that the progestogen, drospirenone is micronized and that the ethinyl estradiol is in the form of extrudable viscous liquid, see col. 10, lines 2-55. Elliesen finally teaches polyvinylpyrrolidone as a suitable excipient for its composition, see col. 11, lines 1-31.

Gast (WO 98/04269) and Elliesen et al. (USPN 5,922,349) taken together do not particularly teach the employment of prodrugs of drospirenone or the particular method of dissolving drospirenone. Nor do they particularly teach that the ethinyl estradiol is micronized.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a prodrug of drospirenone in the compositions of Gast and Elliesen and to dissolve drospirenone. It would have also been obvious to employ ethinyl estradiol in micronized form.

One of ordinary skill in the art would have been motivated to employ known ethinyl estradiol in micronized form because variations or optimizations of the dosage regimen of compounds well known to be administered together in a combination, are considered within the skill of the artisan. Note that the Skilled Artisan would be motivated to employ esters and prodrugs of known actives because they are reasonably expected to possess the same physiological and pharmacological activities. One of ordinary skill in the art would have been motivated to employ micronized drospirenone dissolved by any method because micronized drospirenone is known to be useful in combination compositions as taught by Elliesen.

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Claims 18-19, 21-22, ⁴⁰¹42, 48-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gast (WO 98/04267) Elliesen et al. (USPN 5,922,349).

Gast (WO 98/04267) discloses a combination composition and pharmaceutically acceptable carriers and excipients comprising 23-25 daily dosage units comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estradiol and 3-5 dosage units comprising 5 to 15 micrograms of ethinyl estradiol, see claim 1 and page 9, lines 15-24 in particular.

Elliesen et al. (USPN 5,922,349) teaches an orally administerable pharmaceutical composition comprising ethinyl estradiol (5-15 microgram) as the estrogen and drospirenone (1-3 mg) as the progestogen. Elliesen further teaches that the progestogen, drospirenone is micronized and that the ethinyl estradiol is in the form of extrudable viscous liquid, see col. 10, lines 2-55. Elliesen finally teaches polyvinylpyrrolidone as a suitable excipient for its composition, see col. 11, lines 1-31.

Gast (WO 98/04269) and Elliesen et al. (USPN 5,922,349) taken together do not particularly teach the employment of prodrugs of drospirenone or the particular method of dissolving drospirenone. Nor do they particularly teach that the ethinyl estradiol is micronized.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a prodrug of drospirenone in the compositions of Gast and Elliesen and to dissolve drospirenone. It would have also been obvious to employ ethinyl estradiol in micronized form.

One of ordinary skill in the art would have been motivated to employ known ethinyl estradiol in micronized form because variations or optimizations of the dosage regimen of

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compounds well known to be administered together in a combination, are considered within the skill of the artisan. Note that the Skilled Artisan would be motivated to employ esters and prodrugs of known actives because they are reasonably expected to possess the same physiological and pharmacological activities. One of ordinary skill in the art would have been motivated to employ micronized drospirinone dissolved by any method because micronized drospirinone is known to be useful in combination compositions as taught by Elliesen.

Response to Arguments

Applicant's arguments that none of the Gast references teach drospirinone in micronized form have been considered but are moot in view of the new ground(s) of rejection.

Dr. Lipp's declaration submitted under 35 CFR 1.132 has been considered but is not persuasive to remove the obviousness rejections herein. Dr. Lipp relying on references in appendix B states that micronization does not always increase the solubility of a drug. Note that no data/article regarding drospirinone in micronized form has been submitted to rebut the prima facie case of obviousness. Dr. Lipp further states that given the isomerization of drospirinone at low pHs of the stomach, the Skilled Artisan would not orally administer micronized drospirinone. Note that the Elliesen reference used in the obviousness rejections herein teaches the employment of micronized drospirinone in contraceptive and HRT methods. Therefore the Skilled Artisan would be motivated to micronize the drospirinone. The 132 declaration does not "clearly and convincingly" demonstrate unexpected results or a teaching away by the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The


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examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
May 30, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

6/1/03